

Examiners Geckle and Robinson on the morning of November 25, 1991.

Applicant would like to thank Examiner Geckle for the courtesy extended to Applicant's attorney, Michael Tompkins, in the telephone conversation on October 28, 1991. In the October 28, 1991 telephone conversation, the statement in the Advisory Action which reads "It is deemed particularly relevant that the claims do not require the presence of the microorganism in the food product" was discussed. Examiner Geckle was of the opinion that the "comprising" language employed in the claim could lead to the possibility that the microorganism would not necessarily have to be present. It is Applicant's position that the claim language requires the presence of the microorganism. Examiner Geckle suggested that her supervisor be contacted regarding this matter.

Applicant would also like to thank Examiner Robinson for the courtesy extended to Mr. Tompkins in the two telephone conversations of October 29, 1991 and October 30, 1991. Again, the portion of the Advisory Action dealing with the presence of the microorganism in the food product was discussed. Examiner Robinson indicated that his initial reaction was that the "comprising" language allowed for the presence of other materials, but did not allow for the exclusion of the microorganisms. However, Examiner Robinson indicated that he would prefer that any arguments regarding this matter be submitted in writing. Therefore, Applicant is submitting the present response to the Advisory Action prior to next Monday's personal interview.

During the October 30, 1991 telephone conversation, Examiner Robinson and Mr. Tompkins discussed conducting a personal interview on Monday, November 25, 1991 in the event that there is still any question of whether the pending claims.

NOV 18 1991

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are allowable after submission of the present response to the Advisory Action. Applicant (William Barclay), an officer of the Assignee (Kent Meager), and Applicant's attorney (Mike Tompkins) have arranged to be in Arlington, Virginia during the morning and early afternoon of Monday, November 25, 1991. Because Applicant's attorney's plane departs from Dulles Airport at approximately 3:00 p.m., it would be preferred to have the interview the morning of Monday, November 25, 1991, preferably at 10:00 a.m. Applicant's attorney will contact Examiner Geckle or Examiner Robinson during the week of November 18, 1991 to November 23, 1991 in order to verify the time for the interview.

In the Advisory Action dated September 30, 1991, the Examiner took the position that the proposed amendments would not be entered since they raise new issues with regard to the requirements of 35 U.S.C. §112, first and second paragraph, which would require further search and consideration.

Specifically, the Examiner has taken the position that the amendment to Claim 7, which depends on Claim 1, refers to the "degree of cell rupture," yet there is no requirement for the microorganism to be present in the food product. Applicant respectfully traverses the Examiner's position. It is respectfully pointed out that the claim language does require the presence of the microorganism in the claimed food product. Specifically, Claim 1 reads:

A food product, comprising:

- a) a source of omega-3 highly unsaturated fatty acids comprising microorganisms from the order Thraustochytriales; and
- b) food material. (Emphasis added.)

The claim language as set forth requires the presence of microorganisms in the food product. Although, the term "comprising" is open-ended, presence of the stated material is

NOV 18 1991

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required. Therefore, it is respectfully submitted that the Examiner's objection to Claim 7 has been obviated.

The Examiner has taken the position that the phrase "help prevent oxygen from readily reaching" in Claim 53 is indefinite as to meaning and intent. Claim 53 has been amended to remove any ambiguity. Support for this amendment can be found at page 21, lines 22-38. It is therefore respectfully submitted that the Examiner's objection to Claim 53 has been obviated.

The Examiners are also taking the position that the modifications to Claims 54 and 55 are also indefinite since "less than" is not the equivalent of "up to." It is respectfully submitted that "less than" and "up to" do, indeed, have equivalent meanings when used in the manner the phrases are used in Claims 54 and 55.

Furthermore, the Examiner has taken the position that the proposed Claim 65 adds a new larger grouping of microorganisms which would require further search and consideration. Applicant respectfully submits that this is not the case. Indeed, Claim 65 is narrower than Claim 1 in that it limits the microorganisms from the order Thraustochytriales (as claimed in Claim 1) to only those microorganisms which are of the genus Thraustochytrium, the genus Schizochytrium, and mixtures thereof. This is narrower in scope than Claim 1. Therefore, it is respectfully submitted that the Examiner's objection to Claim 65 has been obviated.

Applicant notes with appreciation that the Examiner has withdrawn the rejection based upon the Long reference. However, the Examiner has maintained all other rejections for reasons of record.

In particular, the Examiner has taken the position that "It is deemed particularly relevant that the claims do not require the presence of the microorganism in the food product."

Applicant respectfully traverses the Examiner's position. Specifically, Independent Claim 1 and the claims dependent on Claim 1 are all limited to food products which contain specific microorganisms. Having established this fact, it becomes readily apparent that the Examiner has not established a prima facie case of obviousness.

The test for obviousness is whether one skilled in the art at the time the invention was unknown, and just before it was made, would consider the claimed invention as a whole obvious in view of the prior art. The Court of Appeals for the Federal Circuit has stated that "The PTO has the burden under section 103 to establish a prima facie case of obviousness.... It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). The Examiner has not shown any teaching or knowledge which would lead the skilled artisan to employ the claimed microorganisms in a food product.

The cited art does not disclose the use of microorganisms which contain omega-3 fatty acids in food products, and, in particular, no cited reference discloses the use of microorganisms of the order Thraustochytriales in food products. Applicant has demonstrated, by way of the Declaration of William R. Barclay dated May 20, 1991, that it would not be obvious to use omega-3 containing microorganisms in food products and, in particular, microorganisms of the order Thraustochytriales in food products, because of the large amount that would be required. Therefore, one skilled in the art would not be led to the use of the microorganisms in food products. Applicant has also pointed out the advantages of eliminating any extraction procedures.

In the Examiner's Office Action dated July 30, 1991, the Examiner took the position that

Applicant's comments concerning extraction of the omega-3 HUFA versus use of the whole cells containing omega-3 HUFA is not found persuasive. Applicant has not demonstrated any difference between the two forms other than what one of ordinary skill would have expected. Long chose to separate out the undesired extraneous material from the fatty acids of interest. Applicant's choice not to extract does not distract from the fact that the reference teaches the same source of the fatty acids as is claimed and further teaches this source in food. No unexpected results are shown in using whole cells versus the extract. (Emphasis added.)

The above quotation demonstrates that the Examiner is employing impermissible hindsight analysis. In particular, the underlined sentence shows that the Examiner is not evaluating the invention, but rather is assuming the invention is known and that comparing that known invention to the prior art. The U.S. Patent Office Board of Appeals and the Court of Appeals for the Federal Circuit have repeatedly stated that such hindsight analysis is inappropriate. Furthermore, the Long reference which the Examiner discussed in the above quotation has been removed from consideration as it is not prior art.

Regarding the primary references which the Examiner is presently relying on, the Examiner stated in the February 14, 1991 Office Action that "Kyle provides the motivation to screen, select and improve culturing conditions to increase the yields of EPA in the microalga genera taught by Ellenbogen et al. as well as its application in the food industry." Neither Ellenbogen et al. nor Kyle disclose or even suggest the use of the claimed microorganisms in a food product. Indeed, Ellenbogen et al. do not suggest any uses for the fatty acids they discovered present in a variety of microorganisms. Furthermore, Kyle discloses that "Our recent work has focused on screening, selecting and improving the EPA yields of several oil-producing microalga species as a prelude to determining if

this source of EPA-containing oil may be of economic importance to the food of pharmaceutical industries." In other words, not only did Kyle not realize that the microorganism itself could be used in the food product, he was not even aware of whether the EPA could be usefully extracted for use in the food of pharmaceutical industries. The fact that Kyle lumped the food and pharmaceutical industries together is further evidence that he did not appreciate the use of the microorganism itself in a food product.

In the present case, the Examiner has shown no reason why one of ordinary skill in the art would employ omega-3 HUFA-containing microorganisms in a food product, much less microorganisms of the order Thraustochytriales. A mere assertion that it would have been obvious, without support for or explanation of such a conclusion is not sufficient. Therefore, it is respectfully submitted that Claim 1 and the claims dependent on Claim 1 are allowable.

The Examiner has further taken the position "that while the culture techniques may be critical for specific strains of the microorganism, there is no evidence that these results would occur across the whole order of the microorganism." Applicants, in the specification, have enabled one in the skill of the art to produce microorganisms of the order Thraustochytriales which can be grown under conditions of low salinity. In independent Claim 58 and the claims dependent thereon, Applicant has claimed such microorganisms for a use as a source of omega-3 fatty acid, both in the form of the whole cell microorganism or in the form of an extract, in a food product. Applicant's specification provides support for such a claim limitation. Applicant has not suggested that all microorganisms will respond to such culture techniques, and therefore Applicant has limited the claims to those which do.

Further, Applicant has demonstrated for the record why it would be advantageous to employ a microorganism which grows in a low salinity culture. Additionally, a potential licensee of Applicant's invention has recently stated that an important reason for their interest in Applicant's technology is because Applicant's claimed microorganisms are able to grow in low salinity solutions. An important secondary consideration of non-obviousness is commercial success.

Therefore, it is respectfully submitted that all claims are in condition for allowance and Applicant respectfully requests the Examiner to pass this case to issue. A request for a one-month extension of time accompanies this response, along with authorization to charge the appropriate fee to Deposit Account 19-1970.

Respectfully submitted,

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NOV 18 1991

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